

## REMARKS

It is respectfully requested that this application be reconsidered in view of the following remarks and that all of the claims remaining be allowed.

### Rejection Under 35 U.S.C. §102:

The rejection of claims 21-25 and 30-34 under 35 U.S.C. §102(e) over Cooper et al. (U.S. Patent No. 6,174,528, hereinafter "the Cooper patent") is respectfully traversed for the reasons set forth below.

The standard of anticipation under 35 U.S.C. §102 is that each and every element of the claim must be found in the cited reference. *In re Marshall* (CCPA 1978), 198 USPQ 344.

The Cooper patent does not teach each and every element of the claimed invention. Claim 21 of the present application is directed to a coiled-coil polypeptide comprising the formula  $(ab_i c_i d e f g_i)_n$ , where  $i=1,2,\dots,n$ , and  $n$  is at least three, said polypeptide being prepared by

- (a) independently inserting an amino acid selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof, into each of the  $a$  and  $d$  positions; and
- (b) selecting a solvent-accessible region of an epitope of a selected natural protein, wherein said region is not in a coiled-coil conformation in its native state, and inserting the amino acids from said region into the  $b_i$ ,  $c_i$ ,  $e_i$ ,  $f_i$  and  $g_i$  positions;

wherein  $(ab_i c_i d e f g_i)_n$  forms a coiled-coil.

Thus, the polypeptide of claim 21 is prepared by inserting amino acids from a pre-selected group into the  $a$  and  $d$  positions of the formula  $(ab_i c_i d e f g_i)_n$  and a solvent-accessible region into the  $b_i$ ,  $c_i$ ,  $e_i$ ,  $f_i$  and  $g_i$  positions. The solvent-accessible region is from an epitope of a

natural protein, wherein the region is not in a coiled-coil conformation in its native state. Claims 22-25 depend from claim 21, thereby reciting all the elements of claim 21.

The Cooper patent teaches that one sequence can be embedded within a second sequence (see, for example, column 2, lines 19-21). Indeed, all examples in the Cooper patents teach the embedding of a short peptide sequence in the middle of a second sequence, resulting in a fusion protein. For instance, in Example 12 of the Cooper patent, a series of 12-mer peptides overlapping by 1 residue was derived from the streptococcal M protein peptide p145, and each 12-mer was embedded into a GCN4 sequence. Thus, the resulting chimeric peptides have a 12 amino acid sequence from p145 flanked by GCN4 sequences. The polypeptides of the claimed invention, on the other hand, contain amino acid residues from a first sequence in the  $b_i$ ,  $c_i$ ,  $e_i$ ,  $f_i$  and  $g_i$  positions, which are interrupted by amino acids from the  $a$  and  $d$  positions.

Furthermore, the Cooper patent does not teach a coiled-coil polypeptide that comprises a region which is not in a coiled-coil conformation in its native state. Instead, the Cooper patent teaches:

In accordance with the present invention, overlapping peptides derived from a conformational epitope are embedded within a peptide having a similar native conformation. (column 2, lines 19-21; emphasis added)

Accordingly, one aspect of the present invention contemplates a chimeric peptide comprising a first amino acid sequence comprising a conformational epitope inserted within a second amino acid sequence wherein said first and second amino acid sequences are derived from peptides, polypeptides or proteins having similar native conformations. (column 2, lines 26-32; emphasis added)

The Cooper patent further teaches that the second amino acid sequence constitutes a "framework peptide" and provides an appropriate conformation for the chimeric peptide (column 2, lines 33-36). In particular, the conformation may be coiled-coil:

In its most preferred embodiment, the framework peptide assumes a  $\alpha$ -helical coiled coil conformation and is, therefore, useful in presenting epitopes present in the first amino acid sequence in a similar conformation, i.e. an  $\alpha$ -helical coiled coil conformation. (column 2, lines 39-43)

Accordingly, a coiled-coil peptide taught by the Cooper patent would contain a first amino acid sequence embedded in a second amino acid sequence, and both sequences are in an  $\alpha$ -helical coiled coil conformation in their native state. In contrast, claims 21-25 of the present application require the  $b_i$ ,  $c_i$ ,  $e_i$ ,  $f_i$  and  $g_i$  positions of the coiled-coil to be occupied by a solvent-accessible region of an epitope of a selected natural protein, wherein said region is not in a coiled-coil conformation in its native state. Nowhere does the Cooper patent teach the insertion of sequences from a non-coiled-coil protein into a coiled-coil framework to prepare a coiled-coil polypeptide.

Similarly, claim 30 of the present application is directed to a coiled-coil polypeptide, comprising an amino acid sequence represented by  $(ab_i c_i d e f_i g_i)_n$ , where

$i=1,2,\dots,n$ , and  $n$  is at least three;

$a$  and  $d$  are amino acids each independently selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof;

$(b_i c_i d e f_i g_i)_n$  is a sequence of amino acids from a solvent-accessible region of an epitope from a selected natural protein, wherein said region is not in a coiled-coil conformation in its native state; and wherein  $(ab_i c_i d e f_i g_i)_n$  forms a coiled coil.

Claims 31-34 depend from claim 30, thus reciting all the elements of claim 30. Again, the Cooper patent does not teach the polypeptides of claims 31-34, e.g., with respect to the region of the polypeptides that is derived from a non-coiled-coil region.

Therefore, the Cooper patent does not teach each and every element of the claimed invention. Since the requirement under 35 U.S.C. §102 is not met, Applicants respectfully request that this rejection be withdrawn.

Allowable Subject Matter

Applicants wish to thank the Examiner for reminding Applicants that claims 26-29 and 35-38 are allowable. As articulated above, Applicants submit that all pending claims are allowable.

Conclusions:

For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested. Allowance of the claims remaining in this application is earnestly solicited.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is invited to call the undersigned at (650) 622-2300.

Respectfully submitted,

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